

116TH CONGRESS
2D SESSION

S. 3734

To provide for a coordinated Federal research initiative to ensure continued United States leadership in engineering biology.

IN THE SENATE OF THE UNITED STATES

MAY 14, 2020

Mrs. GILLIBRAND (for herself, Mr. MARKEY, Mr. RUBIO, and Mr. GARDNER) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

A BILL

To provide for a coordinated Federal research initiative to ensure continued United States leadership in engineering biology.

1 *Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the “Bioeconomy Research
5 and Development Act of 2020”.

6 SEC. 2. FINDINGS.

7 The Congress makes the following findings:

8 (1) Cellular and molecular processes may be
9 used, mimicked, or redesigned to develop new prod-

1 ucts, processes, and systems that improve societal
2 well-being, strengthen national security, and con-
3 tribute to the economy.

4 (2) Engineering biology relies on a workforce
5 with a diverse and unique set of skills combining the
6 biological, physical, chemical, and information
7 sciences and engineering.

8 (3) Long-term research and development is nec-
9 essary to create breakthroughs in engineering biol-
10 ogy. Such research and development requires govern-
11 ment investment as many of the benefits are too dis-
12 tant or uncertain for industry to support alone.

13 (4) Research is necessary to inform evidence-
14 based governance of engineering biology and to sup-
15 port the growth of the engineering biology industry.

16 (5) The Federal Government has an obligation
17 to ensure that ethical, legal, environmental, safety,
18 security, and societal implications of its science and
19 technology research and investment follows policies
20 of responsible innovation and fosters public trans-
21 parency.

22 (6) The Federal Government can play an im-
23 portant role by facilitating the development of tools
24 and technologies to further advance engineering biol-
25 ogy, including user facilities, by facilitating public-

1 private partnerships, by supporting risk research,
2 and by facilitating the commercial application in the
3 United States of research funded by the Federal
4 Government.

5 (7) The United States led the development of
6 the science and engineering techniques that created
7 the field of engineering biology, but due to increasing
8 international competition, the United States is
9 at risk of losing its competitive advantage if does not
10 invest the necessary resources and have a national
11 strategy.

12 (8) A National Engineering Biology Initiative
13 can serve to establish new research directions and
14 technology goals, improve interagency coordination
15 and planning processes, drive technology transfer to
16 the private sector, and help ensure optimal returns
17 on the Federal investment.

18 **SEC. 3. DEFINITIONS.**

19 In this Act:

20 (1) BIOMANUFACTURING.—The term “bio-
21 manufacturing” means the utilization of biological
22 systems to develop new and advance existing prod-
23 ucts, tools, and processes at commercial scale.

24 (2) ENGINEERING BIOLOGY.—The term “engi-
25 neering biology” means the application of engineer-

1 ing design principles and practices to biological sys-
2 tems, including molecular and cellular systems, to
3 advance fundamental understanding of complex nat-
4 ural systems and to enable novel or optimize func-
5 tions and capabilities.

6 (3) INITIATIVE.—The term “Initiative” means
7 the National Engineering Biology Research and De-
8 velopment Initiative established under section 4.

9 (4) OMICS.—The term “omics” refers to the
10 collective technologies used to explore the roles, rela-
11 tionships, and actions of the various types of mol-
12 ecules that make up the cells of an organism.

13 **SEC. 4. NATIONAL ENGINEERING BIOLOGY RESEARCH AND**
14 **DEVELOPMENT INITIATIVE.**

15 (a) IN GENERAL.—The President, acting through the
16 Office of Science and Technology Policy, shall implement
17 a National Engineering Biology Research and Develop-
18 ment Initiative to advance societal well-being, national se-
19 curity, sustainability, and economic productivity and com-
20 petitiveness through—

21 (1) advancing areas of research at the intersec-
22 tion of the biological, physical, chemical, data, and
23 computational sciences and engineering to accelerate
24 scientific understanding and technological innovation
25 in engineering biology;

(2) advancing areas of biomanufacturing research to optimize, standardize, scale, and deliver new products and solutions;

13 (5) supporting risk research, including under
14 subsection (d);

15 (6) supporting the development of novel tools
16 and technologies to accelerate scientific under-
17 standing and technological innovation in engineering
18 biology;

23 (8) accelerating the translation and commer-
24 cialization of engineering biology research and devel-
25 opment by the private sector; and

(9) improving the interagency planning and coordination of Federal Government activities related to engineering biology.

4 (b) INITIATIVE ACTIVITIES.—The activities of the
5 Initiative shall include—

(1) sustained support for engineering biology research and development through—

(A) grants to individual investigators and teams of investigators, including interdisciplinary teams;

(B) projects funded under joint solicitations by a collaboration of no fewer than two agencies participating in the Initiative; and

14 (C) interdisciplinary research centers that
15 are organized to investigate basic research
16 questions, carry out technology development
17 and demonstration activities, and increase un-
18 derstanding of how to scale up engineering biol-
19 ogy processes, including biomanufacturing;

(2) sustained support for databases and related tools, including—

(A) support for curated genomics, epigenomics, and all other relevant omics databases, including plant and microbial databases.

1 that are available to researchers to carry out
2 engineering biology research;

3 (B) development of standards for such
4 databases, including for curation, interoper-
5 ability, and protection of privacy and security;

6 (C) support for the development of com-
7 putational tools, including artificial intelligence
8 tools, that can accelerate research and innova-
9 tion using such databases; and

10 (D) an inventory and assessment of all
11 Federal Government omics databases to identify
12 opportunities for consolidation and inform in-
13 vestment in such databases as critical infra-
14 structure for the engineering biology research
15 enterprise;

16 (3) sustained support for the development, opti-
17 mization, and validation of novel tools and tech-
18 nologies to enable the dynamic study of molecular
19 processes *in situ*, including through—

20 (A) research conducted at Federal labora-
21 tories;

22 (B) grants to investigators at institutions
23 of higher education and other nonprofit re-
24 search institutions; and

(4) education and training of undergraduate and graduate students in engineering biology, in biomanufacturing, in bioprocess engineering, and in areas of computational science applied to engineering biology and in the related ethical, legal, environmental, safety, security, and other societal issues;

(5) activities to develop robust mechanisms for tracking and quantifying the outputs and economic benefits of engineering biology; and

(6) activities to accelerate the translation and commercialization of new products, processes, and technologies by—

18 (A) identifying precompetitive research op-
19 portunities;

(B) facilitating public-private partnerships in engineering biology research and development;

(C) connecting researchers, graduate students, and postdoctoral fellows with entrepreneurs.

1 neurship education and training opportunities;
2 and

3 (D) supporting proof of concept activities
4 and the formation of startup companies includ-
5 ing through programs such as the Small Busi-
6 ness Innovation Research Program and the
7 Small Business Technology Transfer Program.

8 (c) EXPANDING PARTICIPATION.—The Initiative
9 shall include, to the maximum extent practicable, outreach
10 to primarily undergraduate and minority-serving institu-
11 tions about Initiative opportunities, and shall encourage
12 the development of research collaborations between re-
13 search-intensive universities and primarily undergraduate
14 and minority-serving institutions.

15 (d) ETHICAL, LEGAL, ENVIRONMENTAL, SAFETY,
16 SECURITY, AND SOCIETAL ISSUES.—Initiative activities
17 shall take into account ethical, legal, environmental, safe-
18 ty, security, and other appropriate societal issues by—

19 (1) supporting research, including in the social
20 sciences, and other activities addressing ethical,
21 legal, environmental, and other appropriate societal
22 issues related to engineering biology, including inte-
23 grating research on such topics with the research
24 and development in engineering biology, and ensur-
25 ing that the results of such research are widely dis-

1 seminated, including through interdisciplinary engi-
2 neering biology research centers described in sub-
3 section (b)(1);

4 (2) supporting research and other activities re-
5 lated to the safety and security implications of engi-
6 neering biology, including outreach to increase
7 awareness among Federal researchers and federally
8 funded researchers at institutions of higher edu-
9 cation about potential safety and security implica-
10 tions of engineering biology research, as appropriate;

11 (3) ensuring that input from Federal and non-
12 Federal experts on the ethical, legal, environmental,
13 safety, security, and other appropriate societal issues
14 related to engineering biology is integrated into the
15 Initiative; and

16 (4) ensuring, through the agencies and depart-
17 ments that participate in the Initiative, that public
18 input and outreach are integrated into the Initiative
19 by the convening of regular and ongoing public dis-
20 cussions through mechanisms such as workshops,
21 consensus conferences, and educational events, as
22 appropriate.

23 **SEC. 5. INITIATIVE COORDINATION.**

24 (a) INTERAGENCY COMMITTEE.—The President, act-
25 ing through the Office of Science and Technology Policy,

1 shall designate an interagency committee to coordinate en-
2 gineering biology, which shall be co-chaired by the Office
3 of Science and Technology Policy, and include representa-
4 tives from the National Science Foundation, the Depart-
5 ment of Energy, the Department of Defense, the National
6 Aeronautics and Space Administration, the National Insti-
7 tute of Standards and Technology, the Environmental
8 Protection Agency, the Department of Agriculture, the
9 National Institutes of Health, the Bureau of Economic
10 Analysis, and any other agency that the President con-
11 siders appropriate (in this section referred to as the
12 “interagency committee”). The Director of the Office of
13 Science and Technology Policy shall select an additional
14 co-chairperson from among the members of the Inter-
15 agency Committee. The Interagency Committee shall over-
16 see the planning, management, and coordination of the
17 Initiative. The Interagency Committee shall—

18 (1) provide for interagency coordination of Fed-
19 eral engineering biology research, development, and
20 other activities undertaken pursuant to the Initia-
21 tive;

22 (2) establish and periodically update goals and
23 priorities for the Initiative;

24 (3) develop, not later than 12 months after the
25 date of enactment of this Act, and update every 3

1 years, a strategic plan submitted to the Committee
2 on Science, Space, and Technology of the House of
3 Representatives and the Committee on Commerce,
4 Science, and Transportation of the Senate that—

5 (A) guides the activities of the Initiative
6 for purposes of meeting the goals and priorities
7 established under (and updated pursuant to)
8 paragraph (2); and

9 (B) describes—

10 (i) the Initiative's support for long-
11 term funding for interdisciplinary engineer-
12 ing biology research and development;

13 (ii) the Initiative's support for edu-
14 cation and public outreach activities;

15 (iii) the Initiative's support for re-
16 search and other activities on ethical, legal,
17 environmental, safety, security, and other
18 appropriate societal issues related to engi-
19 neering biology including—

20 (I) an applied biorisk manage-
21 ment research plan;

22 (II) recommendations for inte-
23 grating security into biological data
24 access and international reciprocity
25 agreements; and

(III) an evaluation of existing biosecurity governance policies, guidance, and directives for the purposes of creating a unified, adaptable, evidence-based framework to respond to emerging biosecurity challenges created by advances in engineering biology;

(iv) how the Initiative will move results out of the laboratory and into application for the benefit of society and United States competitiveness; and

(v) how the Initiative will measure and track the contributions of engineering biology to United States economic growth and other societal indicators;

(4) develop a national genomic sequencing strategy to ensure engineering biology research fully leverages plant, animal, and microbe biodiversity to enhance long-term innovation and competitiveness in engineering biology in the United States;

(5) propose an annually coordinated interagency budget for the Initiative that is intended to ensure—

1 (A) the maintenance of a robust engineer-
2 ing biology research and development portfolio;
3 and

4 (B) that the balance of funding across the
5 Initiative is sufficient to meet the goals and pri-
6 orities established for the Program;

7 (6) develop a plan to utilize Federal programs,
8 such as the Small Business Innovation Research
9 Program and the Small Business Technology Trans-
10 fer Program as described in section 9 of the Small
11 Business Act (15 U.S.C. 638), in support of the ac-
12 tivities described in section 4(b)(3); and

13 (7) in carrying out this section, take into con-
14 sideration the recommendations of the advisory com-
15 mittee established under section 6, the results of the
16 workshop convened under section 7, existing reports
17 on related topics, and the views of academic, State,
18 industry, and other appropriate groups.

19 (b) ANNUAL REPORT.—Beginning with fiscal year
20 2020, not later than 90 days after submission of the Presi-
21 dent's annual budget request and each fiscal year there-
22 after, the interagency committee shall prepare and submit
23 to the Committee on Science, Space, and Technology of
24 the House of Representatives and the Committee on Com-

1 merce, Science, and Transportation of the Senate a report

2 that includes—

3 (1) a summarized agency budget in support of
4 the Initiative for the fiscal year to which such budg-
5 et request applies, and for the then current fiscal
6 year, including a breakout of spending for each
7 agency participating in the Program and for the de-
8 velopment and acquisition of any research facilities
9 and instrumentation; and

10 (2) an assessment of how Federal agencies are
11 implementing the plan described in subsection
12 (a)(3), including—

13 (A) a description of the amount and num-
14 ber of awards made under the Small Business
15 Innovation Research Program and the Small
16 Business Technology Transfer Program (as de-
17 scribed in section 9 of the Small Business Act
18 (15 U.S.C. 638)) in support of the Initiative;
19 and

20 (B) a description of the amount and num-
21 ber of projects funded under joint solicitations
22 by a collaboration of no fewer than 2 agencies
23 participating in the Initiative.

24 (c) INITIATIVE OFFICE.—

- 1 (1) IN GENERAL.—The President shall establish
2 an Initiative Coordination Office, with a Director
3 and full-time staff, which shall—
4 (A) provide technical and administrative
5 support to the interagency committee and the
6 advisory committee established under section 6;
7 (B) serve as the point of contact on Fed-
8 eral engineering biology activities for govern-
9 ment organizations, academia, industry, profes-
10 sional societies, State governments, interested
11 citizen groups, and others to exchange technical
12 and programmatic information;
13 (C) oversee interagency coordination of the
14 Initiative, including by encouraging and sup-
15 porting joint agency solicitation and selection of
16 applications for funding of activities under the
17 Initiative;
18 (D) conduct public outreach, including dis-
19 semination of findings and recommendations of
20 the advisory committee established under sec-
21 tion 6, as appropriate;
22 (E) serve as the coordinator of ethical,
23 legal, environmental, safety, security, and other
24 appropriate societal input; and

22 SEC. 6. ADVISORY COMMITTEE.

23 (a) IN GENERAL.—The President, acting through the
24 Office of Science and Technology Policy, shall designate
25 or establish an advisory committee on engineering biology

1 research and development (in this section referred to as
2 the “advisory committee”) to be composed of not fewer
3 than 12 members, including representatives of research
4 and academic institutions, industry, and nongovernmental
5 entities, who are qualified to provide advice on the Initiative.
6

7 (b) ASSESSMENT.—The advisory committee shall as-
8 sess—

9 (1) the current state of United States competi-
10 tiveness in engineering biology, including the scope
11 and scale of United States investments in engineer-
12 ing biology research and development in the inter-
13 national context;

14 (2) current market barriers to commercializa-
15 tion of engineering biology products, processes, and
16 tools in the United States;

17 (3) progress made in implementing the Initiative;
18

19 (4) the need to revise the Initiative;

20 (5) the balance of activities and funding across
21 the Initiative;

22 (6) whether the strategic plan developed or up-
23 dated by the interagency committee established
24 under section 5 is helping to maintain United States
25 leadership in engineering biology;

1 (7) the management, coordination, implementa-
2 tion, and activities of the Initiative; and

3 (8) whether ethical, legal, environmental, safety,
4 security, and other appropriate societal issues are
5 adequately addressed by the Initiative.

6 (c) REPORTS.—Beginning not later than 2 years
7 after the date of enactment of this Act, and not less fre-
8 quently than once every 3 years thereafter, the advisory
9 committee shall submit to the President, the Committee
10 on Science, Space, and Technology of the House of Rep-
11 resentatives, and the Committee on Commerce, Science,
12 and Transportation of the Senate, a report on—

13 (1) the findings of the advisory committee's as-
14 essment under subsection (b); and

15 (2) the advisory committee's recommendations
16 for ways to improve the Initiative.

17 (d) APPLICATION OF FEDERAL ADVISORY COM-
18 MITTEE ACT.—Section 14 of the Federal Advisory Com-
19 mittee Act (5 U.S.C. App.) shall not apply to the Advisory
20 Committee.

21 **SEC. 7. EXTERNAL REVIEW OF ETHICAL, LEGAL, ENVIRON-**
22 **MENTAL, SAFETY, SECURITY, AND SOCIETAL**
23 **ISSUES.**

24 (a) IN GENERAL.—Not later than 6 months after the
25 date of enactment of this Act, the Director of the National

1 Science Foundation shall seek to enter into an agreement
2 with the National Academies of Sciences, Engineering,
3 and Medicine to conduct a review, and make recommenda-
4 tions with respect to, the ethical, legal, environmental,
5 safety, security, and other appropriate societal issues re-
6 lated to engineering biology research and development.

7 The review shall include—

8 (1) an assessment of the current research on
9 such issues;

10 (2) a description of the research gaps relating
11 to such issues;

12 (3) recommendations on how the Initiative can
13 address the research needs identified pursuant to
14 paragraph (2); and

15 (4) recommendations on how engineering biol-
16 ogy researchers can best incorporate considerations
17 of ethical, legal, environmental, safety, security, and
18 other societal issues into the development of research
19 proposals and the conduct of research.

20 (b) REPORT TO CONGRESS.—The agreement entered
21 into under subsection (a) shall require the National Acad-
22 emies of Sciences, Engineering, and Medicine to, not later
23 than 2 years after the date of the enactment of this Act—

24 (1) submit to the Committee on Science, Space,
25 and Technology of the House of Representatives and

1 the Committee on Commerce, Science, and Trans-
2 portation of the Senate a report containing the find-
3 ings and recommendations of the review conducted
4 under subsection (a); and

5 (2) make a copy of such report available on a
6 publicly accessible website.

7 (c) ALTERNATE CONTRACT SCIENTIFIC ORGANIZA-
8 TION.—

9 (1) IN GENERAL.—If the Director is unable to
10 enter into an agreement described in subsection (a)
11 with the National Academy of Sciences before the
12 date specified in such subsection on terms acceptable
13 to the Director, the Director shall seek to enter into
14 such an agreement with another appropriate sci-
15 entific organization that—

16 (A) is not part of the Government;
17 (B) operates as a not-for-profit entity; and
18 (C) has expertise and objectivity com-
19 parable to that of the National Academy of
20 Sciences.

21 (2) TREATMENT.—If the Director enters into
22 an agreement with another organization as described
23 in paragraph (1), any reference in this subsection to
24 the National Academy of Sciences shall be treated as
25 a reference to the other organization.

1 SEC. 8. AGENCY ACTIVITIES.

2 (a) NATIONAL SCIENCE FOUNDATION.—As part of
3 the Initiative, the National Science Foundation shall—

4 (1) support basic research in engineering biology through individual grants and through interdisciplinary research centers;

5 (2) support research on the environmental, legal, ethical, and social implications of engineering
6 biology;

7 (3) provide support for research instrumentation for engineering biology disciplines, including
8 support for research, development, optimization and validation of novel technologies to enable the dynamic study of molecular processes in situ;

9 (4) support curriculum development and research experiences for secondary, undergraduate,
10 and graduate students in engineering biology and biomanufacturing; and

11 (5) award grants, on a competitive basis, to enable institutions to support graduate students and
12 postdoctoral fellows who perform some of their engineering biology research in an industry setting.

13 (b) DEPARTMENT OF COMMERCE.—As part of the
14 Initiative, the Director of the National Institute of Standards and Technology shall—

1 (1) establish a bioscience research program to
2 advance the development of standard reference ma-
3 terials and measurements and to create new data
4 tools, techniques, and processes necessary to advance
5 engineering biology and biomanufacturing;

6 (2) provide access to user facilities with ad-
7 vanced or unique equipment, services, materials, and
8 other resources to industry, institutions of higher
9 education, nonprofit organizations, and government
10 agencies to perform research and testing; and

11 (3) provide technical expertise to inform the po-
12 tential development of guidelines or safeguards for
13 new products, processes, and systems of engineering
14 biology.

15 (c) DEPARTMENT OF ENERGY.—As part of the Ini-
16 tiative, the Secretary of Energy shall—

17 (1) conduct and support research, development,
18 demonstration, and commercial application activities
19 in engineering biology, including in the areas of syn-
20 thetic biology, advanced biofuel development,
21 biobased materials, and environmental remediation;

22 (2) support the development, optimization and
23 validation of novel, scalable tools and technologies to
24 enable the dynamic study of molecular processes in
25 situ; and

1 (3) provide access to user facilities with ad-
2 vanced or unique equipment, services, materials, and
3 other resources, as appropriate, to industry, institu-
4 tions of higher education, nonprofit organizations,
5 and government agencies to perform research and
6 testing.

7 (d) DEPARTMENT OF DEFENSE.—As part of the Ini-
8 tiative, the Secretary of Defense shall—

9 (1) conduct and support research and develop-
10 ment in engineering biology and associated data and
11 information sciences;

12 (2) support curriculum development and re-
13 search experiences in engineering biology and associ-
14 ated data and information sciences across the mili-
15 tary education system, to include service academies,
16 professional military education, and military grad-
17 uate education; and

18 (3) assess risks of potential national security
19 and economic security threats relating to engineering
20 biology.

21 (e) NATIONAL AERONAUTICS AND SPACE ADMINIS-
22 TRATION.—As part of the Initiative, the National Aero-
23 nautics and Space Administration shall—

24 (1) conduct and support basic and applied re-
25 search in engineering biology, including in synthetic

1 biology, and related to Earth and space sciences,
2 aeronautics, space technology, and space exploration
3 and experimentation, consistent with the priorities
4 established in the National Academies' decadal sur-
5 veys; and

6 (2) award grants, on a competitive basis, that
7 enable institutions to support graduate students and
8 postdoctoral fellows who perform some of their engi-
9 neering biology research in an industry setting.

10 (f) DEPARTMENT OF AGRICULTURE.—As part of the
11 Initiative, the Secretary of Agriculture shall—

12 (1) support research and development in engi-
13 neering biology, including in synthetic biology and
14 biomaterials;

15 (2) award grants through the National Institute
16 of Food and Agriculture; and

17 (3) support development conducted by the Agri-
18 cultural Research Service.

19 (g) ENVIRONMENTAL PROTECTION AGENCY.—As
20 part of the Initiative, the Environmental Protection Agen-
21 cy shall support research on how products, processes, and
22 systems of engineering biology will affect or can protect
23 the environment.

24 (h) DEPARTMENT OF HEALTH AND HUMAN SERV-
25 ICES.—

1 (1) NATIONAL INSTITUTES OF HEALTH.—As
2 part of the Initiative, the Director of the National
3 Institutes of Health shall—

4 (A) support research and development to
5 advance the understanding and application of
6 engineering biology for human health, including
7 in synthetic biology, cell and tissue engineering,
8 computational biology, and artificial intel-
9 ligence;

10 (B) support and accelerate the application
11 of biomedical research and technologies through
12 cross-disciplinary collaboration and training
13 programs;

14 (C) support research on ethical, legal, safe-
15 ty, and societal implications of emerging bio-
16 technologies; and

17 (D) award grants on a competitive basis,
18 that enable institutions to support graduate
19 students and postdoctoral fellows who perform
20 some of their engineering biology research
21 across multiple disciplinary departments.

22 (2) FOOD AND DRUG ADMINISTRATION.—As
23 part of the Initiative, the Commissioner of Food and
24 Drugs shall—

- 1 (A) support research and evaluation of
2 safety, potency, and efficacy of novel biologic
3 products and biomanufacturing technologies;
4 and
5 (B) ensure the timely development of
6 screening methods to evaluate safety and secu-
7 rity of new biological products and processes.

○